

AMENDED IN SENATE AUGUST 17, 2009

AMENDED IN SENATE JULY 13, 2009

AMENDED IN SENATE JUNE 16, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 1397

Introduced by Assembly Member Hill
(Principal coauthor: Senator Leno)

February 27, 2009

An act to amend Section 1644.5 of the Health and Safety Code, relating to tissue donation, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 1397, as amended, Hill. Tissue donation.

Existing law prohibits the transfer of any tissues, as defined, into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), human T lymphotropic virus-1 (HTLV-1), and syphilis, except as provided.

Existing law requires that all donors of sperm be screened and found nonreactive under the above provisions, except as provided. Under existing law, a sperm donor who has tested reactive for HIV or HTLV-1 may be used for insemination or advanced reproductive technology for a recipient who has tested negative only after processing to minimize the infectiousness of the sperm. The State Department of Public Health is required to adopt regulations by January 1, 2010, regulating facilities that perform this processing.

Existing law further requires the physician providing insemination or advanced reproductive technologies to, among other things, inform the recipient that the processing may not eliminate the risk of infection, that the sperm may be tested to ensure that it is free from HIV or HTLV-1, and about the potential adverse effects of testing on the sperm.

This bill would *also* require the physician to inform the recipient that ~~she should establish an~~ *must provide documentation to the physician providing insemination or advanced reproductive technology services prior to treatment that she has established an ongoing physician relationship with another physician to provide for her medical care during and after completion of fertility services* and about the medical guidelines for testing after use of sperm from an HIV or HTLV reactive donor.

Under existing law, the physician performing insemination or advanced reproductive technology is required to provide prophylactic treatments, followup testing, and monitoring, as specified, to the recipient to minimize the risk of infection.

This bill would remove those requirements but would require the physician to recommend followup testing of the recipient for HIV and HTLV, as specified.

Existing law allows the use of sperm from a donor who has tested reactive for HIV or HTLV-1 if the recipient has also previously been documented with HIV or HTLV-1 and where mutual consent has been obtained.

This bill would remove this provision. The bill would also make all of the provisions above applicable to donors who have tested reactive for any of the human T lymphotropic viruses.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1644.5 of the Health and Safety Code is
- 2 amended to read:
- 3 1644.5. (a) No tissues shall be transferred into the body of
- 4 another person by means of transplantation, unless the donor of
- 5 the tissues has been screened and found nonreactive by laboratory
- 6 tests for evidence of infection with HIV, agents of viral hepatitis

1 (HBV and HCV), human T lymphotropic virus (HTLV), and
2 syphilis, except as provided in subdivision (c). The department
3 may adopt regulations requiring additional screening tests of donors
4 of tissues when, in the opinion of the department, the action is
5 necessary for the protection of the public, donors, or recipients.

6 (b) Notwithstanding subdivision (a), infectious disease screening
7 of blood and blood products shall be carried out solely in
8 accordance with Article 2 (commencing with Section ~~1601~~ 1602.5)
9 of Chapter 4.

10 (c) All donors of sperm shall be screened and found nonreactive
11 as required under subdivision (a), except in the following instances:

12 (1) A recipient of sperm, from a sperm donor known to the
13 recipient, may waive a second or other repeat testing of that donor
14 if the recipient is informed of the requirements for testing donors
15 under this section and signs a written waiver.

16 (2) A recipient of sperm may consent to therapeutic insemination
17 of sperm or use of sperm in other advanced reproductive
18 technologies even if the sperm donor is found reactive for hepatitis
19 B, hepatitis C, syphilis, HIV or HTLV if the sperm donor is the
20 spouse of, partner of, or designated donor for that recipient. The
21 physician providing insemination or advanced reproductive
22 technology services shall advise the donor and recipient of the
23 potential medical risks associated with receiving sperm from a
24 reactive donor. The donor and the recipient shall sign a document
25 affirming that each comprehends the potential medical risks of
26 using sperm from a reactive donor for the proposed procedure and
27 that each consents to it. Copies of the document shall be placed in
28 the medical records of the donor and the recipient.

29 (3) (A) Sperm whose donor has tested reactive for syphilis may
30 be used for the purposes of insemination or advanced reproductive
31 technology only after the donor has been treated for syphilis. Sperm
32 whose donor has tested reactive for hepatitis B may be used for
33 the purposes of insemination or advanced reproductive technology
34 only after the recipient has been vaccinated against hepatitis B.

35 (B) (i) Sperm whose donor has tested reactive for HIV or HTLV
36 may be used for the purposes of insemination or advanced
37 reproductive technology for a recipient testing negative for HIV
38 or HTLV only after the donor's sperm has been effectively
39 processed to minimize the infectiousness of the sperm for that

1 specific donation and where informed and mutual consent has
2 occurred.

3 (ii) Not later than January 1, 2010, the department shall adopt
4 regulations regulating facilities that perform sperm processing,
5 pursuant to this subparagraph, that prescribe standards for the
6 handling and storage of sperm samples of carriers of HIV, HTLV,
7 or any other virus as deemed appropriate by the department. The
8 department may propose to adopt, as initial regulations, guidelines
9 made by the American Society for Reproductive Medicine. Notice
10 of the department's proposed adoption of the regulations shall be
11 posted on the department's Internet Web site for at least 45 days.
12 Public comment shall be accepted by the department for at least
13 30 days after posting of the notice. If a member of the public
14 requests a public hearing during the 30-day comment period, the
15 hearing shall be held prior to the adoption of the regulations.
16 Comments received shall be considered prior to the adoption of
17 the final initial regulations. The department may modify any
18 guidance published by the American Society for Reproductive
19 Medicine based on the comments received. Adoption of initial
20 regulations by the department pursuant to this subdivision shall
21 not be subject to the rulemaking requirements of Chapter 3.5
22 (commencing with Section 11340) of Part 1 of Division 3 of Title
23 2 of the Government Code and written responses to public
24 comments shall not be required. Updates to the regulations shall
25 be adopted pursuant to the same process. Until the department
26 adopts these regulations, facilities that perform sperm processing
27 pursuant to this section shall follow facility and sperm processing
28 guidelines for the reduction of viral transmission developed by the
29 American Society for Reproductive Medicine. Nothing in this
30 section shall prevent the department from monitoring and
31 inspecting facilities that process sperm to ensure adherence to the
32 regulations, or, until regulations are adopted, to the guidelines set
33 forth by the American Society for Reproductive Medicine.

34 (iii) Prior to insemination or other advanced reproductive
35 technology services, the physician providing the services shall
36 inform the recipient of sperm from a donor who has tested reactive
37 for HIV or HTLV of all of the following:

38 (I) That sperm processing may not eliminate all of the risks of
39 HIV or HTLV transmission.

1 (II) That the sperm may be tested to determine whether or not
2 it is reactive for HIV or HTLV.

3 ~~(III) That the recipient should establish an ongoing physician~~
4 ~~relationship, which the physician providing services shall~~
5 ~~document.~~

6 *(III) That the recipient must provide documentation to the*
7 *physician providing insemination or advanced reproductive*
8 *technology services prior to treatment that she has established an*
9 *ongoing relationship with another physician to provide for her*
10 *medical care during and after completion of fertility services.*

11 (IV) The medical guidelines of the American Society for
12 Reproductive Medicine regarding followup testing for HIV and
13 HTLV after use of sperm from an HIV or HTLV reactive donor
14 and that ~~the recommendations regarding~~ followup testing will be
15 documented in the recipient's medical record.

16 (iv) The physician providing insemination or advanced
17 reproductive technology services shall also verify, and document
18 in the recipient's medical record, that the donor of sperm who tests
19 reactive for HIV or HTLV is under the care of a physician
20 managing the HIV or HTLV.

21 (v) The physician providing insemination or advanced
22 reproductive technology services shall recommend to the physician
23 who will be providing ongoing care to the recipient recommended
24 followup testing for HIV and HTLV according to the medical
25 guidelines of the American Society for Reproductive Medicine,
26 which shall be documented in the recipient's medical record.

27 (vi) In the event that the recipient becomes HIV or HTLV
28 positive, the physician assuming ongoing care of the recipient shall
29 treat or provide information regarding referral to a physician who
30 can provide ~~that information and~~ ongoing treatment of the HIV or
31 HTLV.

32 (4) The penalties of Section 1621.5 shall not apply to a sperm
33 donor covered under this subdivision.

34 (d) Subdivision (a) shall not apply to the transplantation of tissue
35 from a donor who has not been tested or, with the exception of
36 HIV and HTLV, has been found reactive for the infectious diseases
37 listed in subdivision (a) or for which the department has, by
38 regulation, required additional screening tests, if both of the
39 following conditions are satisfied:

1 (1) The physician and surgeon performing the transplantation
2 has determined any one or more of the following:

3 (A) Without the transplantation the intended recipient will most
4 likely die during the period of time necessary to obtain other tissue
5 or to conduct the required tests.

6 (B) The intended recipient already is diagnosed with the
7 infectious disease for which the donor has tested positive.

8 (C) The symptoms from the infectious disease for which the
9 donor has tested positive will most likely not appear during the
10 intended recipient's likely lifespan after transplantation with the
11 tissue or may be treated prophylactically if they do appear.

12 (2) Consent for the use of the tissue has been obtained from the
13 recipient, if possible, or if not possible, from a member of the
14 recipient's family, or the recipient's legal guardian. For purposes
15 of this section, "family" shall mean spouse, adult son or daughter,
16 either parent, adult brother or sister, or grandparent.

17 (e) Human breast milk from donors who test reactive for agents
18 of viral hepatitis (HBV and HCV), HTLV, HIV, or syphilis shall
19 not be used for deposit into a milk bank for human ingestion in
20 California.

21 SEC. 2. This act is an urgency statute necessary for the
22 immediate preservation of the public peace, health, or safety within
23 the meaning of Article IV of the Constitution and shall go into
24 immediate effect. The facts constituting the necessity are:

25 To help prevent the spread of HIV, at the earliest possible time,
26 it is necessary that this legislation take immediate effect.